

Chapter 1

Introduction

1.1. Purpose.

This manual provides details on the United States Army Corps of Engineers (USACE) procedures for the design, production, certification, and use of Performance Evaluation (PE) samples in the USACE Environmental Quality Assurance (QA) Program. PE samples are an important part of laboratory validation to ensure that quality data are obtained according to proper Chemical Data Quality Management (CDQM) activities. Quality of chemical data is critical to decision making for USACE environmental compliance and restoration programs. (See USACE 200-1-1, "Validation of Analytical Chemistry Laboratories," for details on lab validation and EM 200-1-6, "Chemical Quality Assurance for HTRW Projects," for CDQM information.)

Specifically, the PE samples discussed in this manual are used to:

- Test the ability of a laboratory to generate data of specified quality required by projects or regulators.
- Evaluate initial and continuous laboratory performance related to a contract/project.
- Ensure quality compliance in testing and maintaining overall data quality.
- Assess selection of appropriate analytical methods and laboratories.
- Assure that decisions affecting public health are based upon accurate and precise data generated by reliable laboratories.
- Meet qualifications for contractual purposes.
- Assist laboratories to improve their overall performance over time.
- Meet requirements of certification.
- Monitor laboratory performance on a routine basis.

1.2. Applicability.

This manual applies to Headquarters USACE (HQUSACE) elements, major subordinate commands (MSC), districts, laboratories, and field operating activities (FOA) having responsibility for in-house or contracted projects involving chemical testing of environmental media or chemical wastes. This includes, but is not limited to, execution of the following programs: Defense Environmental Restoration Program (DERP), Base Realignment and Closure (BRAC), Installation Environmental Compliance, Military Construction, Superfund, Civil Works, work for others including Defense Logistics Agency (DLA), Department of Energy (DOE), etc., and any other construction projects involving hazardous, toxic, and/or radioactive wastes.

Pertinent manual contents for various groups are listed below:

- PE Program Manager and PE Sample Suppliers: manufacture and use of PE samples.
- District customers, HQUSACE, and laboratories: how to request PE samples and participate in proficiency testing.
- Other branches of Department of Defense (DOD), other Federal agencies, and interested parties (commercial laboratories): scientific validity and legal defensibility of the PE samples and proficiency testing.

1.3. Distribution Statement.

This manual and any future revisions shall be approved for public release and unlimited distribution.

1.4. References.

References are listed in Appendix A.

1.5. Manual Overview and Scope.

This manual consists of six chapters and six appendices.

Chapter 1 presents an overview.

Chapter 2 introduces types of PE samples currently available from the USACE.

Chapter 3 discusses PE sample design.

Chapter 4 describes the manufacturing process of PE samples.

Chapter 5 describes PE sample certification process.

Chapter 6 describes the use of PE samples in the USACE Environmental QA Program.

The USACE Environmental PE Program is intended to cover all types of environmental analyses including chemistry, radiochemistry, biology, and microbiology in various environmental matrices. However, this manual applies primarily to chemistry proficiency testing of water and soil. The manual will be updated when PE samples for other types of environmental analyses are developed and used.

1.6. Acronyms and Definitions.

See Appendix B for acronyms, abbreviations, and symbols. Definitions comply with International Organization for Standardization (ISO), American National Standards Institute (ANSI), American Society for Quality (ASQ), and American Society for Testing and Materials (ASTM) usage.

The remainder of this chapter describes responsibility of groups in the PE program, fees and funding, and manual amendment.

1.7. Roles, Responsibilities, and Qualifications.

Distinct roles and responsibilities of five major parties in the PE Program are described below including Program Oversight Authority, Program Manager, PE Sample Providers, Customers, and Participating Laboratories.

1.7.1. Program Oversight Authority. The HQUSACE in Washington, DC, is responsible for oversight of the PE Program and final approval of major policies and operating procedures of the USACE Environmental Laboratory Validation Program. The HQUSACE annually determines the PE program budget and funding sources.

1.7.2. Program Manager. The Program Manager must have the technical expertise, administrative capacity, and financial resources to implement and operate a proficiency testing program. The qualifications of the Program Manager shall comply with the requirements of ISO 10011-2. The Program Manager shall follow the guidelines of ISO 10011 and 58 to inspect PE Sample Providers, at a minimum, on a biennial basis.

The USACE Hazardous, Toxic and Radioactive Waste Center of Expertise (USACE HTRW-CX) in Omaha, Nebraska, manages the USACE Environmental Laboratory Validation Program. Responsibilities include program development and implementation, PE Sample Provider approval, authorization for design and production of new and existing PE samples, and coordination of the PE Program participants.

1.7.3. Customers. USACE Project Managers or Contracting Officer Representatives (PM/COR) are the main customers of the PE Program. PM/COR from other Federal government agencies are potential customers. The customers are responsible for initiating laboratory validation processes and establishing project-specific Data Quality Objectives (DQO), which are considered when specifying PE samples. Customers may also be responsible for providing project-specific funding to support general laboratory validation activities including proficiency testing with PE samples.

1.7.4. PE Sample Providers. The quality system, testing facilities, and operating procedures of the PE Sample Providers shall conform with ISO 9000 series of standards and Guides 25 (17025), 34, 35, and 65. PE Sample Providers involve several government agencies including two environmental laboratories under USACE Environmental Research and Development Center (ERDC) and United States Environmental Protection Agency (USEPA). The PE Program may be supplemented by commercial sources. The Providers are responsible for the design, production, certification, and distribution of PE samples that meet the guidelines or requirements described in this manual and provide technical support to the Program Manager.

1.7.5. Participating Laboratories. Participating laboratories shall conform with ISO 9000 series of standards, ISO Guide 25 (17025), and USACE EM 200-1-1 requirements. Laboratories involved in proficiency testing shall explicitly follow the PE sample analysis requirements and data reporting schedule (see Section 6.1.5 of Chapter 6). Participating laboratories are responsible for PE sample analysis and data reporting costs.

1.8. Fees, Budget, and Funding.

1.8.1. Fees. The unit cost of PE samples includes material and labor costs for development, production, and shipment of PE samples; evaluation of PE results; and preparation of PE reports. A fee schedule is issued each fiscal year on PE unit costs that may be billable to individual customers.

1.8.2. Budget Request and Funding. Budget requests to HQUSACE should be made annually by the Program Manager and include proposed tasks such as PE program operation and PE sample development. Depending on environmental programs, funding is on a yearly or project-specific basis.

Mixed funding for proficiency testing will be used if multiple funding sources are available. For projects with unavailable funds from the Program Manager office or non-USACE entities, customers are responsible for costs except for PE sample analysis and data reporting (participating laboratory's responsibility).

1.9. Effective Date and Amendment.

This manual is effective upon approval by the HQUSACE and shall remain in effect until superseded or terminated.

The manual's guidelines are supported by standard operating procedures (SOPs) that reflect specific day-to-day scientific and business procedures. These SOPs are prepared by the participants of the USACE Laboratory Validation Program and are updated frequently.